## REMARKS

### *Status of the Claims*

Claims 1, 2, 10-13, 16-22 and 41-88 were pending in the present application.

Claims 16-22, 48-54, 61-67 and 75-81 were withdrawn from consideration.

Claims 1, 2, 10-13, 41-47, 55-60, 68-74 and 82-88 were rejected.

By way of this amendment, claims 1, 55, 68, 82 and 83 have been amended.

Upon entry of this amendment, claims 1, 2, 10-13, 16-22 and 41-88 will be pending.

### *Summary of the Amendment*

Claim 1 has been amended to delete the term "functional" when referring to fragments. In addition, claim 1 has been amended to delete one of two recitations of the phrase "does not provide the negative signal associated with wild type human CD80 C region interactions with human CTLA4" as being redundant, and moving the phrase "possesses costimulatory activity of wild type CD80" to a more logical location within the claim.

Claim 55 has been amended to delete the term "functional" consistent with the amendment to claim 1. Moreover, the phrase "does not provide the negative signal associated with wild type human CD80 C region interactions with human CTLA4" has been deleted as being redundant since claim 1 recites the phrase and claim 55 is dependent on claim 1.

Claim 68 has been amended to delete the term "functional" consistent with the amendment to claim 1.

Claims 82 and 83 have been amended to correct and obvious error and insert the term "sequence" which was inadvertently omitted when the claims were added.

No new matter has been added.

### *Claim Objections*

Claims 82 and 83 have been objected to as containing an obvious error. Claims 82 and 83 have been amended to correct the error and the objection is obviated. Withdrawal of the objection is respectfully requested.

***Claim Rejections Under 35 U.S.C. §112, Second Paragraph***

Claims 1-2, 10-13, 41-47, 55-60, 68-74 and 82-88 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. comply with the written description requirement. It is asserted that the term "functional fragment" is unclear.

The claims have been amended to delete reference to "functional" when referring to fragments. The rejection is moot. Withdrawal of the rejection is respectfully requested.

***Claim Rejections Under 35 U.S.C. §112, First Paragraph***

Claims 1-2, 10-13, 41-47, 55-60, 68-74 and 82-88 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted that the introduction of the phrase "all or part of the CD80 region" is new matter. Applicants note that the claim refers to "all or part of the CD80 C region." This subject matter is fully and clearly set forth throughout the specification such as for example in the first paragraph of page 6 of the published PCT application. Clearly, the term is not new matter. The subject matter contained in the claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Withdrawal of the rejection is respectfully requested.

Claims 1-2, 10-13, 41-47, 55-60, 68-74 and 82-88 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. It is asserted that while the specification is enabling for a nucleic acid molecule comprising the various domains, "functional fragments" are not enabled.

First, Applicants respectfully point out that the rejection as indicated does not apply to claim 2 which does not refer to functional fragments.

Second, the claims have been amended to delete the term "functional." The claims recite that the protein must 1) possess costimulatory activity of wild type CD80 and 2) not provide the negative signal associated with wild type CD80 C region interactions with CTLA4. These are the functional limitations of the claims and there is no need to refer to fragments of the particular

regains as being functional or not. As amended, the claims are clear and definite and it is equally clear that the claimed subject matter is enabled. Withdrawal of the rejection is respectfully requested.

Claims 13, 47, 60 and 74 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. It is asserted that the specification does not enabling a "vaccine or attenuated vaccine" comprising the nucleic acid molecule of the invention.

Singh does not support the assertion that adjuvants are unpredictable. Rather, Singh points out that toxicity problems make many adjuvants unsuitable. Toxicity is not an objective concept but rather a relative analysis whereby the FDA determines whether the benefits outweigh the risks associated with toxicity. It is well established that the standards for patentability are different than those used by regulatory agencies. Applicants respectfully assert that, for the purposes of assessing patentability, the criteria is whether or not Singh establishes that adjuvant activity is unpredictable. In fact, Singh reports the great breadth and utility of adjuvant technology and rather than suggesting that the field is unpredictable, clearly supports the notion that adjuvants are an active field where the discovery of a new adjuvant is not unexpected.

The claims are enabled. Withdrawal of the rejection is respectfully requested.

***Claim Rejections Under 35 U.S.C. § 102***

Claims 1-2, 10-13, 41-47 and 82-88 have been rejected under 35 U.S.C. 102(b) as being anticipated by Linsley et al (U.S. Patent 5, 580,756). Applicants respectfully disagree.

Linsley describes a construct having amino acids 1-215 of the extracellular domain of CD80 (see column 27, lines 16-19). Table 6 of the instant application discloses the specific residues of CD80 critical for binding T cell surface receptor CTLA-4. These specific residues of CD80 bind to the T cell surface receptor CTLA-4 to produce the negative signal that the present invention necessarily does not produce. Each of these critical residues is contained within the span of residues included in the construct disclosed in Linsley. That is, the Linsley construct

contains the residues of the C region critical for binding T cell surface receptor CTLA-4 and produces the negative signal that is a product of the binding. Claim 1 clearly recites that the mutant CD80 does not provide the negative signal associated with wild type human CD80 C region interactions with human CTLA4. Linsley contains the wild type human CD80 C region that interacts with human CTLA4. The constructs in Linsley do not anticipate the claims. Every element of the claims is not found in Linsley. Withdrawal of the rejection is respectfully requests.

***Conclusion***

The claims are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

/Mark DeLuca, Reg. No. 33,229/
Mark DeLuca
Registration No. 33,229

Dated: July 2, 2007
PEPPER HAMILTON, LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183
Telephone: 610-640-7855
Facsimile: 610-640-7835